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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,077	06/01/2005	David Duncan Heath	JAMES68.008APC	8641

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

BERRIOS, JENNIFER A

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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05/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/517,077	Applicant(s) HEATH, DAVID DUNCAN	
	Examiner Jennifer A. Berrios	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

.0DETAILED ACTION

Examiner has changed since the previous action, Examiner Jennifer Berríos will continue the prosecution of the application.

This Office Action is in response to Applicant's amendment/remarks/response filed 5/27/2008 wherein claims 1 and 5 have been amended.

Objections Withdrawn

Applicants' arguments, filed 5/27/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant's arguments with respect to claims 1-10 and 31 have been considered but are moot in view of the new ground(s) of rejection. The limitations of the newly added claims are different in breadth and scope, and therefore the rejections from the previous Office Action, mailed 2/25/2008, have been withdrawn.

1. Applicant's arguments with respect to the rejection under 35 USC 112 – 2nd Paragraph has being indefinite have been considered and are considered persuasive, as such the rejection has been withdrawn.
2. Applicant's arguments with respect to Hashmi teaching that the dose released in the booster should be kept small to prevent desensitization to occur and as such teaches away from the instant claims (Pg 5, Paragraph 3) is not found persuasive. Although Hashmi does teach this, it isn't the sole teaching of the reference, it also

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teaches that devices can be manipulated to include different release at different concentrations, as shown in the 103 rejection below.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claim 1-10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashmi et al (WO 01/07079, pub date: 2/1/2001).
4. Regarding claims 1-3 and 5-9, Hashmi teaches a vaccine formulation providing for the extended release of antigenic material over time. The release profile of the different embodiments can be varied, allowing a single administration to establish active immunity in an animal (Abstract). The antigenic material will be released from the carrier system over a period of time after introduction of the vaccine into the subject (Pg 3, lines 25-26). The at least one antigenic substance will be dispersed in a pharmacologically acceptable carrier (Pg 20, claim 1). Hashmi contemplates an embodiment in which the release rate is substantially constant for the intended life of

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the vaccine, other than the possible tailing off near the end of the life of the vaccine (Pg 5, lines 1-2). Hashmi also contemplates that another variation is to periodically supplement a relatively constant rate with burst of higher release, used to trigger the immune system to remain highly active over time (Pg 10, lines 7-10). It is also suggested that the shape of the device can be chosen to affect both the initial release rates and the effect of any tailing off thereof (Pg 12, lines 23-25).

5. A further variation is for the device to have multiple layers, or graduated layers. This can allow for differing release rate profiles merely by adding layers of different solubility and/or release rates, or containing different concentrations of active material. For example there may be a core layer allowing a relatively high release rate, surrounding this may be a further dissolvable layer though with only a low release of active material (Pg 12, lines 26-32), thus suggesting progressively increasing doses with one single administration/device. Hashmi further teaches that the vaccine delay can exceed 24hrs and also 5days (Pg 21, claim 15-16).

6. Regarding claims 4, 10 and 31, although Hashmi does not present examples of what the increasing doses should be. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the increasing dosages taught by Hashmi through routine experimentation. One of skill in the art would have been motivated to find the most effective process for the vaccination.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JB

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615